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(54) **ADMINISTRATION OF CPAP TREATMENT PRESSURE IN PRESENCE OF APNEA**

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(63) Continuation of application No. 10/281,743, filed on Oct. 28, 2002, now Pat. No. 6,817,361, which is a continuation-in-part of application No. 09/531,915, filed on Mar. 21, 2000, now Pat. No. 6,502,572, which is a continuation-in-part of application No. 09/008,743, filed on Jan. 19, 1998, now Pat. No. 6,367,474.

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(52) **U.S. Cl.** **128/204.23**; 128/204.18; 128/204.21

(58) **Field of Classification Search** 128/204.18, 128/204.21, 204.22, 204.23
See application file for complete search history.

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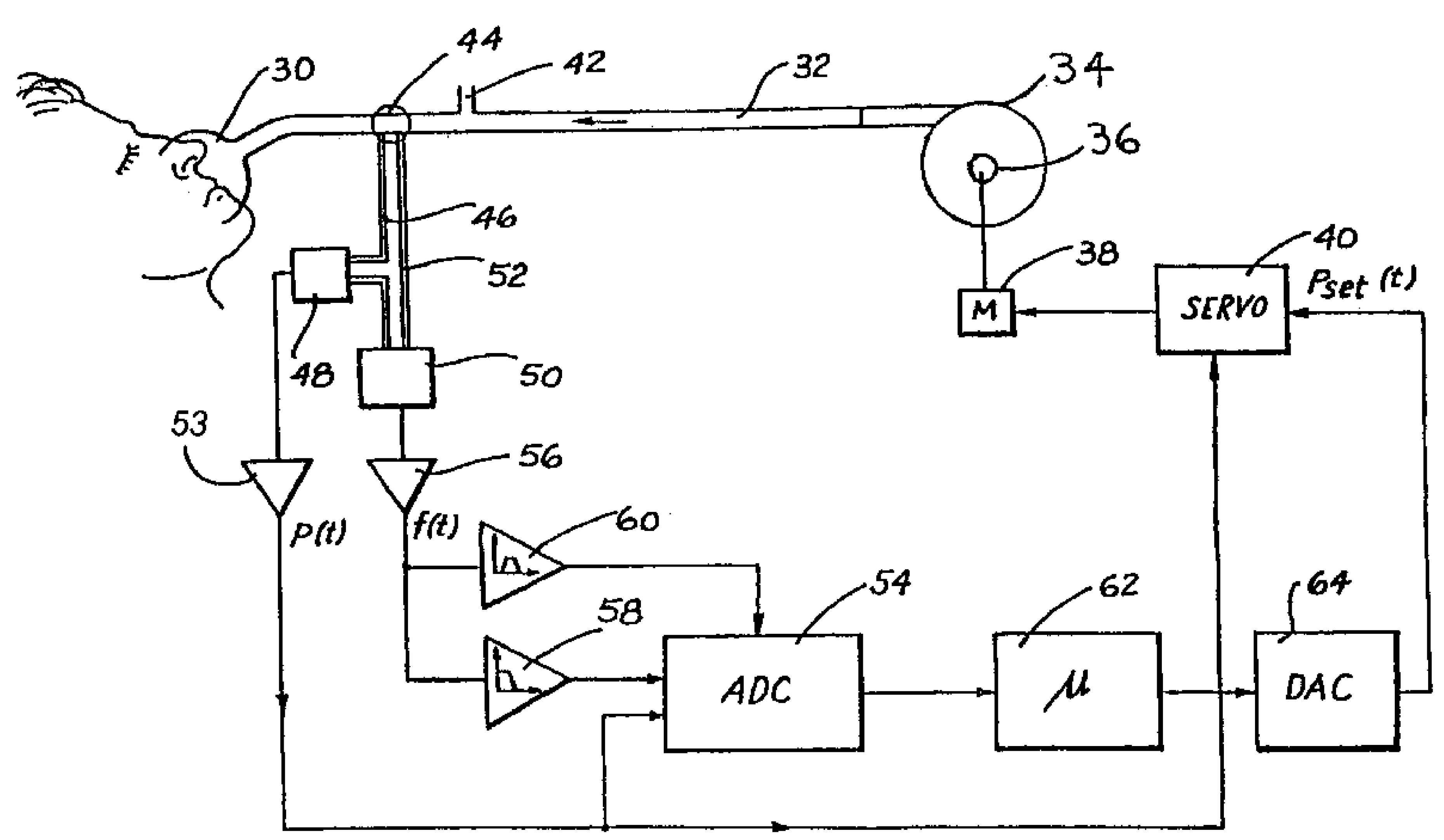
(57) **ABSTRACT**

CPAP treatment apparatus is disclosed having a controllable flow generator (**34**, **38**, **40**) operable to produce breathable gas at a treatment pressure elevated above atmosphere to a patient by a delivery tube (**32**) coupled to a mask (**30**) having connection with a patient's airway. A sensor (**44**, **50**, **56**, **58**) generates a signal representative of patient respiratory flow, that is provided to a controller (**54**, **62**, **64**). The controller (**54**, **62**, **64**) is operable to determine the occurrence of an apnea from a reduction in respiratory airflow below a threshold, and if an apnea has occurred, to determine the duration of the apnea and to cause the flow generator (**34**, **38**) to increase the treatment pressure. In one preferred form the increase in pressure is zero if the treatment pressure before the apnea exceeds a pressure threshold. Below the pressure threshold the increase in pressure is an increasing function of the duration of the apnea multiplied by the difference between the pressure threshold and the current treatment pressure.

17 Claims, 6 Drawing Sheets



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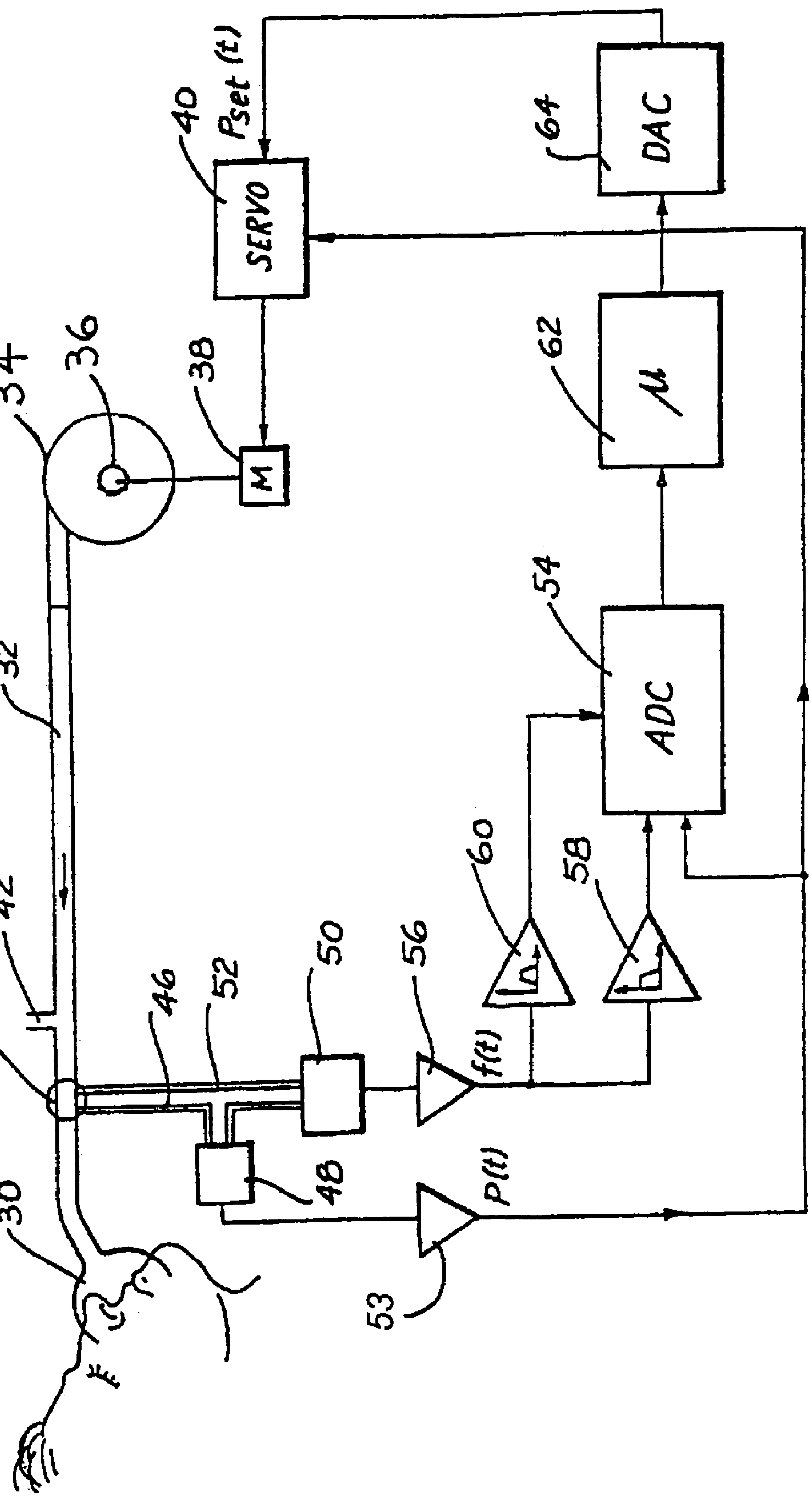
30
32
34
36
38
M
40
SERVO
Pset (t)
42
44
46
48
50
52
53
P(t)
54
ADC
56
f(t)
58
60
62
μ
64
DAC

FIG. 1

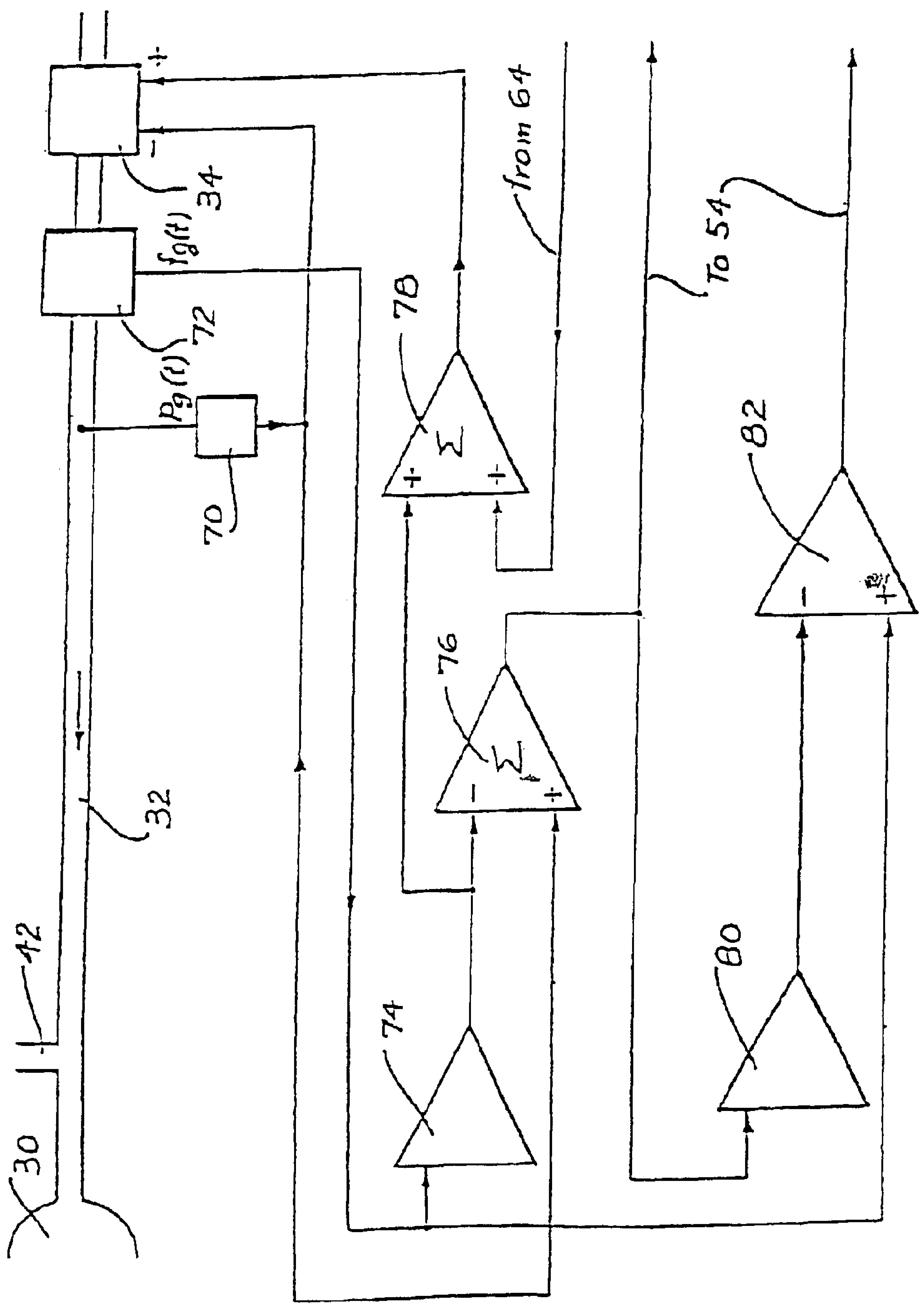

FIG. 2

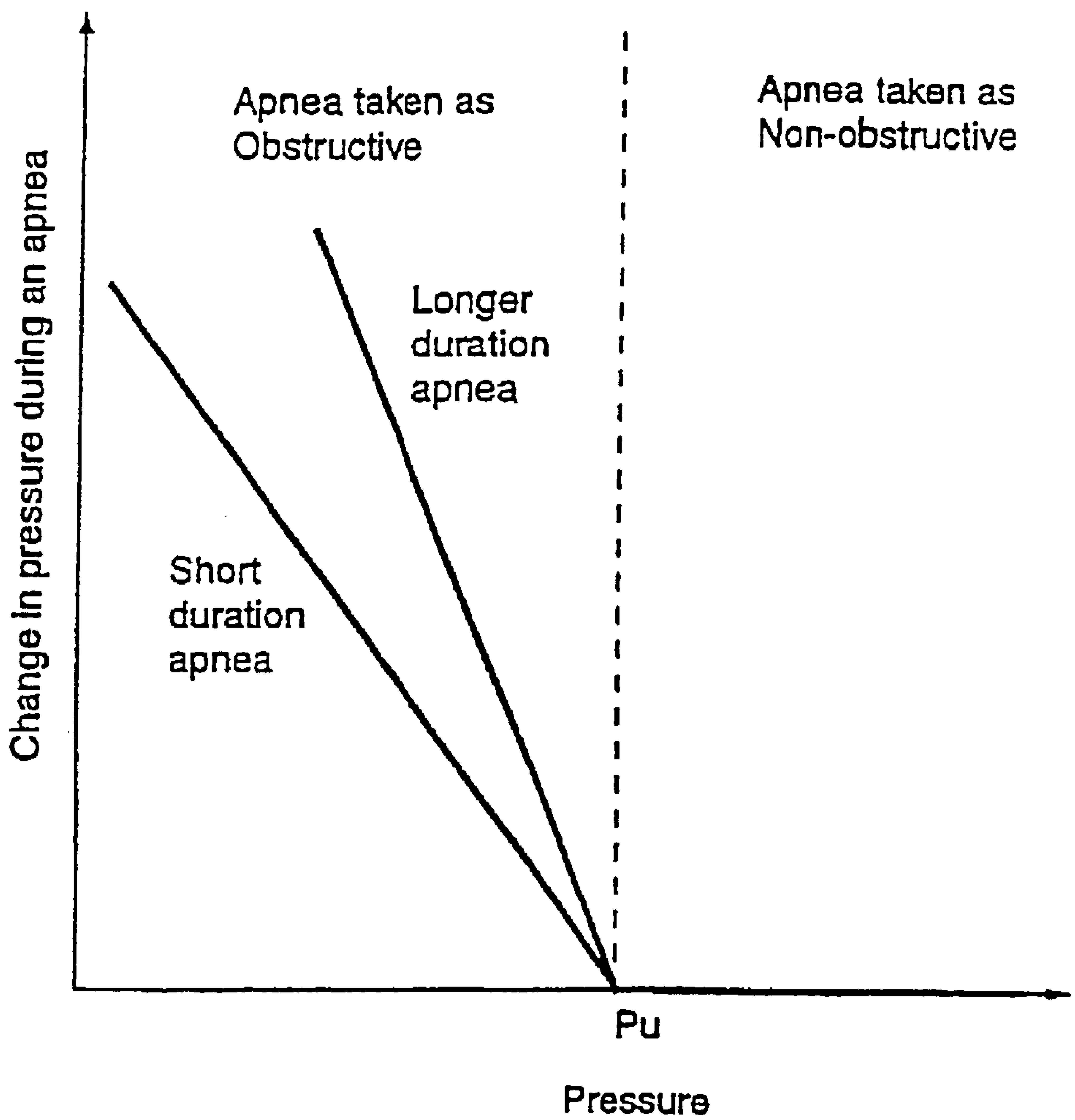
Apnea taken as Obstructive
Apnea taken as Non-obstructive
Change in pressure during an apnea
Longer duration apnea
Short duration apnea
Pu
Pressure

FIG. 3

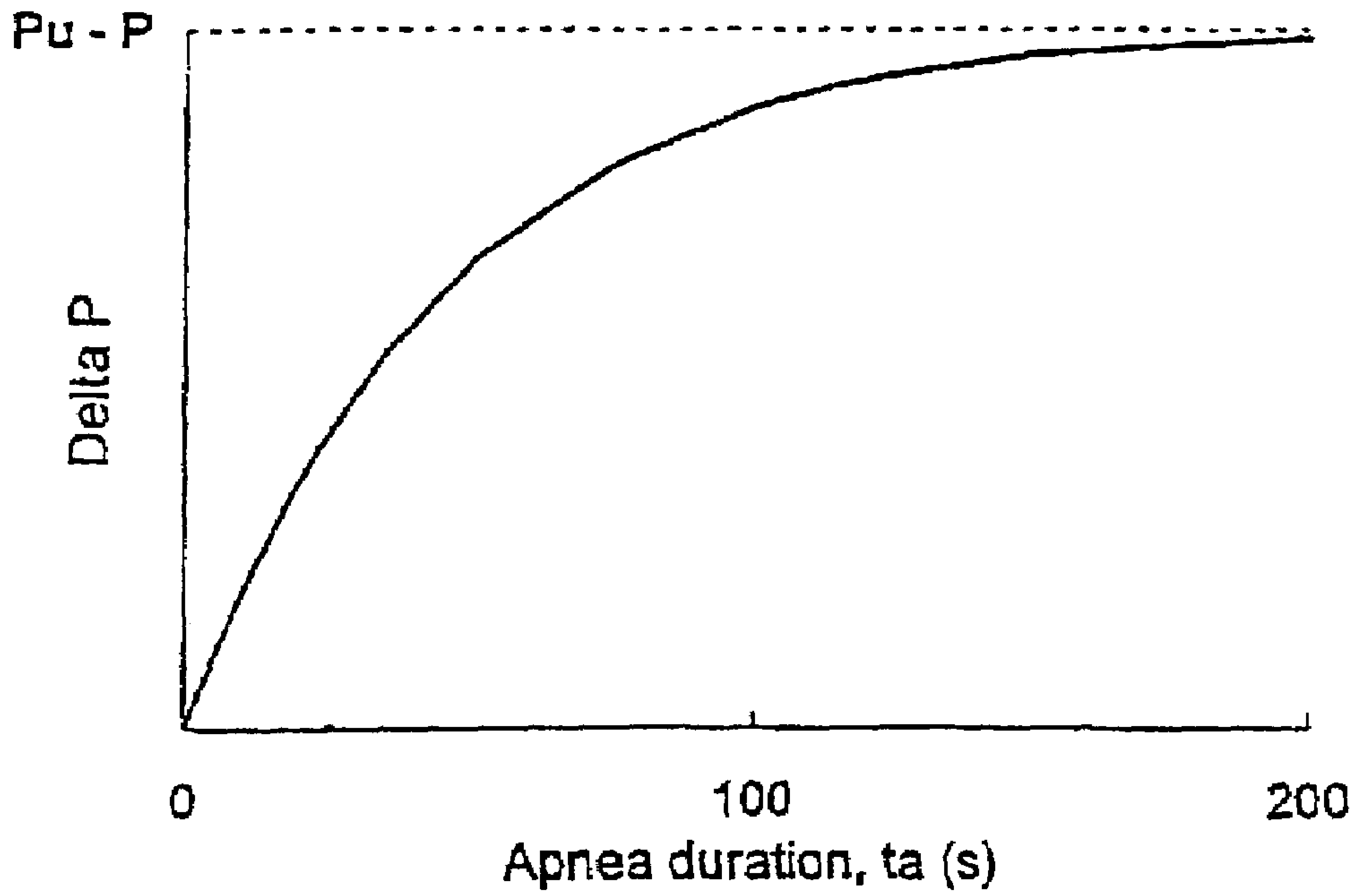

FIG. 4

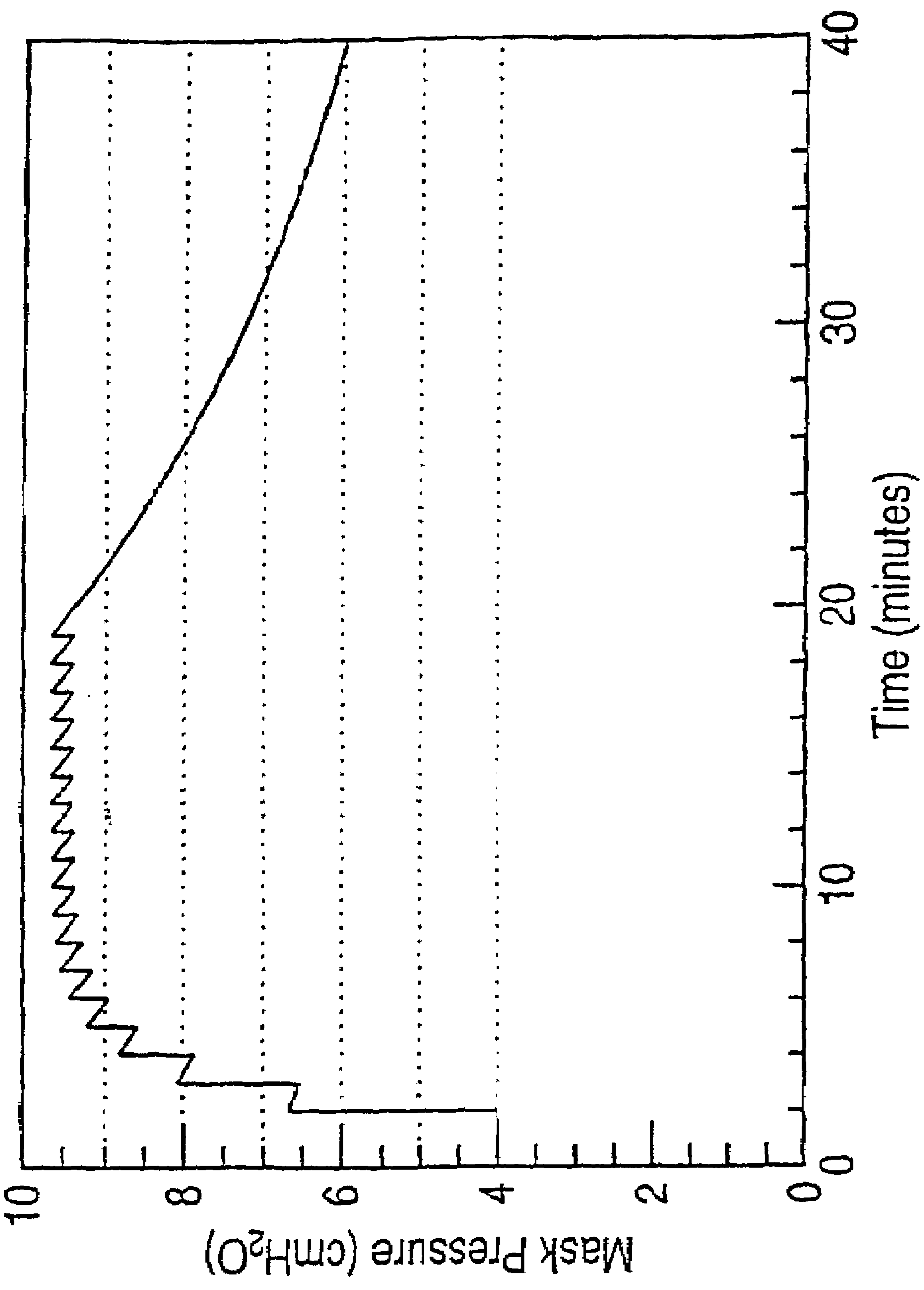

FIG. 5

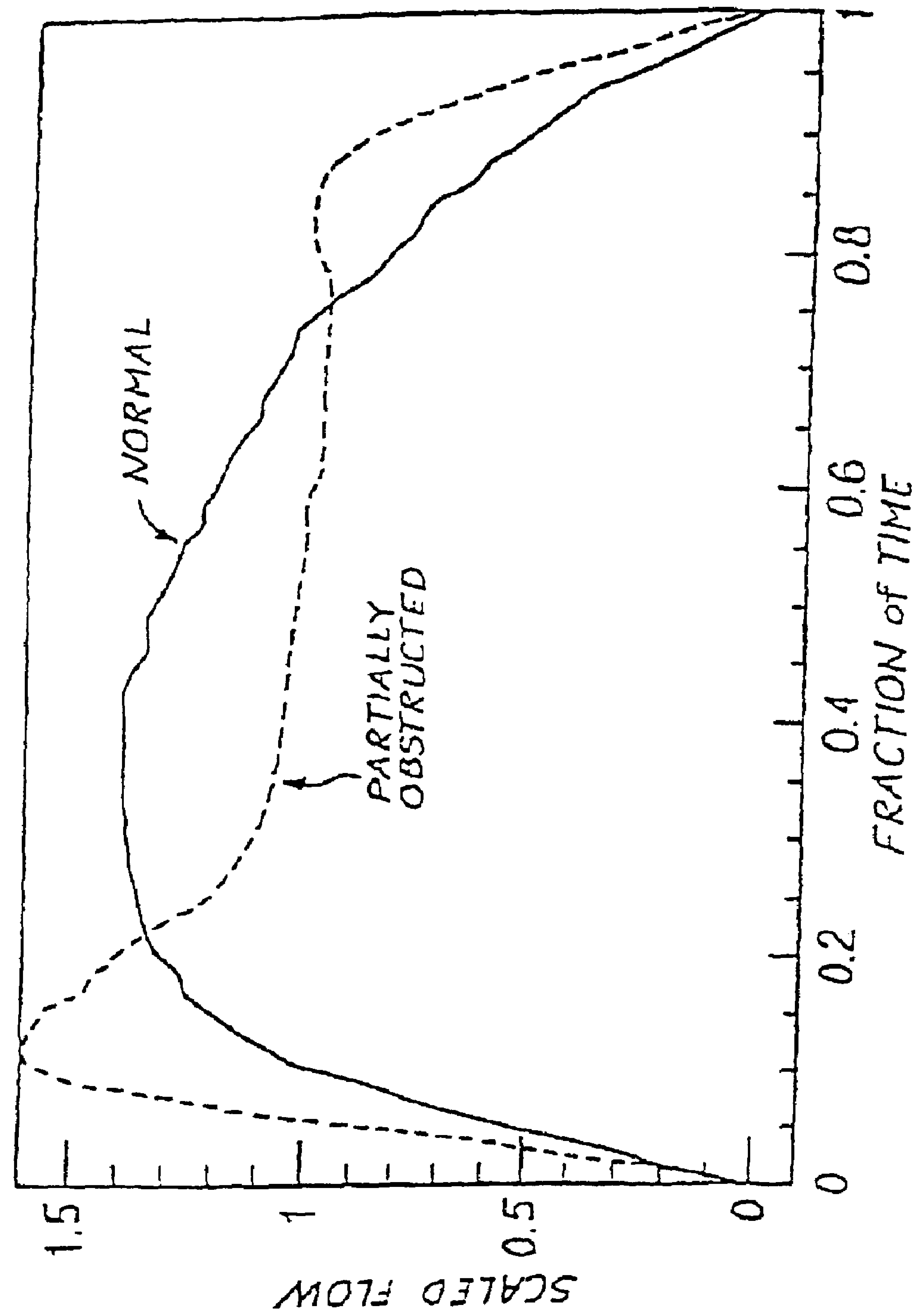
NORMAL
PARTIALLY OBSTRUCTED
SCALED FLOW
FRACTION of TIME
0
0.2
0.4
0.6
0.8
1
0
0.5
1
1.5

FIG. 6

ADMINISTRATION OF CPAP TREATMENT PRESSURE IN PRESENCE OF APNEA

This application is a continuation of application Ser. No. 10/281,743, filed Oct. 28, 2002. now U.S. Pat. No. 6,817, 361, issued Nov. 16, 2004, which is a continuation of application Ser. No. 09/531,915, filed Mar. 21, 2000, now U.S. Pat. No. 6,502,572, issued Jan.7, 2003, which is a continuation-in part of application Ser. No. 09/008,743, filed Jan. 19, 1998, now U.S. Pat. No. 6,367,474, issued Apr. 9, 2002, entitled "Administration of CPAP Treatment Pressure in Presence of Apnea".

FIELD OF THE INVENTION

This invention relates to the administration of continuous positive airway pressure (CPAP) treatment for partial or complete upper airway obstruction.

BACKGROUND OF THE INVENTION

In the Sleep Apnea syndrome a person stops breathing during sleep. Cessation of airflow for more than 10 seconds is called an "apnea". Apneas lead to decreased blood oxygenation and thus to disruption of sleep. Apneas are traditionally (but confusingly) categorized as either central, where there is no respiratory effort, or obstructive, where there is respiratory effort. With some central apneas, the airway is open, and the subject is merely not attempting to breathe. Conversely, with other central apneas and all obstructive apneas, the airway is closed. The occlusion is usually at the level of the tongue or soft palate. The airway may also be partially obstructed (i.e., narrowed or partially patent). This also leads to decreased ventilation (hypopnea), decreased blood oxygenation and disturbed sleep.

The common form of treatment of these syndromes is the administration of Continuous Positive Airway Pressure (CPAP). The procedure for administering CPAP treatment has been well documented in both the technical and patent literature. An early description can be found in U.S. Pat. No. 4,944,310 (Sullivan). Briefly stated. CPAP treatment acts as a pneumatic splint of the airway by the provision of a positive pressure usually in the range 4–20 cmH_2O. The air is supplied to the airway by a motor driven blower whose outlet passes via an air delivery hose to a nose (or nose and/or mouth) mask sealingly engaged to a patient's face. An exhaust port is provided in the delivery tube proximate to the mask. The mask can take the form of a nose and/or face mask or nasal prongs, pillows or cannulae.

Various techniques are known for sensing and detecting abnormal breathing patterns indicative of obstructed breathing. U.S. Pat. No. 5,245,995 (Sullivan et al.), for example, generally describes how snoring and abnormal breathing patterns can be detected by inspiration and expiration pressure measurements made while a subject is sleeping, thereby leading to early indication of preobstructive episodes or other forms of breathing disorder. Particularly, patterns of respiratory parameters are monitored, and CPAP pressure is raised on the detection of pre-defined patterns to provide increased airway pressure to, ideally, subvert the occurrence of the obstructive episodes and the other forms of breathing disorder.

Automatic detection of partial upper airway obstruction and pre-emptive adjustment of nasal CPAP pressure works to prevent frank obstructive apneas in the majority of subjects with obstructive sleep apnea syndrome. However, some subjects with severe disease progress directly from a stable open upper airway to a closed airway apnea with complete airway closure, with little or no intervening period of partial obstruction. Therefore it is useful for an automatically adjusting CPAP system to also respond to a closed airway apnea by an increase in CPAP pressure. However, it is not desirable to increase CPAP pressure in response to open airway apneas, firstly because this leads to an unnecessarily high pressure, and secondly because the high pressure can reflexly cause yet further open airway apneas, leading to a vicious circle of pressure increase.

One method for distinguishing open airway apneas (requiring no increase in pressure) from closed airway apneas (requiring a pressure increase) is disclosed in commonly owned European Publication No. 0 651 971 A1 (corresponding to U.S. Pat. No. 5,704,345). During an apnea, the mask pressure is modulated at 4 Hz with an amplitude of the order of 1 cmH_2O, the induced airflow at 4 Hz is measured, and the conductance of the airway is calculated. A high conductance indicates an open airway. This 'forced oscillation method' requires the ability to modulate the mask pressure at 4 Hz, which increases the cost of the device. Furthermore, the method does not work in the presence of high leak, and can falsely report that the airway is closed if the subject has a high nasal or intrapulmonary resistance.

The present invention is directed to overcoming or at least ameliorating one or more of the foregoing disadvantages in the prior art.

SUMMARY OF THE INVENTION

Therefore, the invention discloses a method for the administration of CPAP treatment pressure comprising the steps of:

supplying breathable gas to the patient's airway at a treatment pressure:

determining a measure of respiratory airflow; and

determining the occurrence of an apnea from a reduction in the measure of respiratory airflow below a threshold, and if having occurred,

(i) determining the duration of the apnea; and

(ii) increasing the treatment pressure by an amount which is an increasing function of the duration of the apnea, and a decreasing function of the treatment pressure immediately before the apnea.

The invention further discloses CPAP treatment apparatus comprising:

a controllable flow generator operable to produce breathable gas at a pressure elevated above atmosphere;

a gas delivery tube coupled to the flow generator;

a patient mask coupled to the tube to receive said breathable gas from the flow generator and provide said gas, at a desired treatment pressure, to the patient's airway;

a controller operable to receive input signals and to control operation of said flow generator and hence the treatment pressure; and

sensor means located to sense patient respiratory airflow and generate a signal input to the controller from which patient respiratory airflow is determined;

and wherein said controller is operable to determine the occurence of an apnea from a reduction in said respiratory airflow below a threshold, and if having occurred, to determine the duration of said apnea and cause said flow generator to increase CPAP treatment pressure by an amount that is an increasing function of said apnea duration, and a decreasing function of the treatment pressure immediately prior to said apnea.

The invention yet further provides CPAP treatment apparatus comprising:

a controllable flow generator operable to produce breathable gas to be provided to a patient at a treatment pressure elevated above atmosphere; and

a controller operable to receive input signals representing patient respiratory airflow, and to control operation of said flow generator and hence the treatment pressure;

and wherein said controller is operable to determine the occurence of an apnea

from a reduction in said respiratory airflow below a threshold, and, if having occurred,

to determine the duration of said apnea and cause said flow generator to increase CPAP

treatment pressure by an amount that is an increasing function of said apnea duration, and a decreasing function of the treatment pressure immediately prior to said apnea.

Preferably, the increase in treatment pressure is zero if the treatment pressure before the apnea exceeds a pressure threshold. The increase in pressure below the pressure threshold can be an increasing function of the duration of the apnea, multiplied by the difference between the pressure threshold and the current treatment pressure. Further, the increasing function of apnea duration is linear on apnea duration. Advantageously, said increasing function of apnea duration is zero for zero apnea duration, and exponentially approaches an upper limit as apnea duration goes to infinity.

The occurrence of an apnea can be determined by calculating the RMS respiratory airflow over a short time interval, calculating the RMS respiratory airflow over a longer time interval, and declaring an apnea if the RMS respiratory airflow over the short time interval is less than a predetermined fraction of the RMS respiratory airflow over the longer time interval. There also can be the further step or action of reducing the treatment pressure towards an initial treatment pressure in the absence of a further apnea.

In a preferred form, said sensor means can comprise a flow sensor, and said controller derives respiratory airflow therefrom.

In one preferred form said initial treatment pressure is 4 cmH_2O, said measure of respiratory airflow is the two second moving average RMS airflow, and said threshold is 25% of the RMS airflow over the preceding 5 minutes. In this preferred form, no increase in pressure is made for apneas of less than 10 seconds duration, or for apneas where the treatment pressure immediately prior to the apnea is more than 10 cmH_2O, but otherwise, the lower the treatment pressure immediately prior to the apnea, and the longer the apnea, the greater the increase in treatment pressure, up to a maximum of 8 cmH_2O per minute of apnea. In this preferred form, if there is no apnea the treatment pressure is gradually reduced towards the initial minimum pressure with a time constant of 20 minutes.

The method and apparatus can advantageously be used in concert with one or more other methods for determining the occurrence of partial upper airway obstruction, such that either complete or partial upper airway obstruction can lead to an increase in pressure, but once there is no longer either complete or partial obstruction, the pressure will gradually reduce towards the initial minimum pressure.

In one particularly preferred form, partial obstruction is detected as either the presence of snoring; or the presence of characteristic changes in the shape of the inspiratory flow-vs-time curve indicative of inspiratory airflow limitation.

The method and apparatus can also advantageously be used in concert with the 'forced oscillation method' for measuring airway patency (referred to above as European Publication No. 0 651 971 A1, U.S. Pat. No. 5,704,345 whose disclosure is hereby incorporated by reference), in which the CPAP pressure is modulated with an amplitude of for example 1 cmH_2O at 4 Hz, the induced airflow at 4 Hz is measured, the conductance of the airway calculated by dividing the amplitude of the induced airflow by the pressure modulation amplitude, and the additional requirement imposed that the treatment pressure is only increased if said conductance is greater than a threshold.

Closed airway apneas are most likely to occur at low CPAP pressures, because high CPAP pressures splint the airway partially or completely open, whereas pressure-induced open airway apneas are most likely to occur at high CPAP pressures, at least partially because high CPAP pressures increase lung volume and thereby stimulate the Hering-Breuer reflex, leading to inhibition of breathing. Therefore, the lower the existing CPAP pressure, the more likely an apnea is to be of the closed airway variety, and the more appropriate it is to increase the treatment pressure, whereas the higher the existing CPAP pressure, the more likely an apnea is to be of the open airway variety, and the more appropriate it is to leave the CPAP pressure unchanged. Generally apneas of less than 10 seconds duration are regarded as non-pathological, and there is no need to increase CPAP pressure, whereas very long apneas require treatment. The present invention will correctly increase the CPAP pressure for most closed airway apneas, and correctly leave the CPAP pressure unchanged for most open airway apneas.

The present invention can be combined with an independent pressure increase in response to indicators of partial upper airway obstruction such as snoring or changes in shape of the inspiratory flow-time curve. In this way it is possible in most subjects to achieve pre-emptive control of the upper airway, with pressure increases in response to partial upper airway obstruction preventing the occurrence of closed airway apneas. In the minority of subjects in whom pre-emptive control is not achieved, this combination will also correctly increase the CPAP pressure in response to those closed airway apneas that occur at low CPAP pressure without prior snoring or changes in the shape of the inspiratory flow-time curve. Furthermore, the combination will avoid falsely increasing the CPAP pressure in response to open airway apneas induced by high pressure.

Some open airway apneas can occur at low pressure. By combining the forced oscillation method with the present invention, with the additional requirement that there be no increase in pressure if the forced oscillation method detects an open airway, false increases in pressure in response to open airway apneas at low pressure will be largely avoided.

BRIEF DESCRIPTION OF THE DRAWINGS

Embodiments of the invention will now be described with reference to the accompanying drawings, in which:

FIG. **1** shows, in diagrammatic form, apparatus embodying the invention;

FIG. **2** shows an alternative arrangement of the apparatus of FIG. **1**;

FIG. **3** shows a plot of two pressure change characteristics as a function of apnea duration;

FIG. **4** shows a plot of the apnea duration function;

FIG. **5** shows a graph of CPAP treatment pressure versus time for a preferred embodiment of the invention; and

FIG. **6** shows a graph of scaled (normalized) air flow with time for normal and partially obstructed inspiration.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

FIG. **1** shows, in diagrammatic form, CPAP apparatus in accordance with one embodiment. A mask **30**, whether either a nose mask and/or a face mask, is sealingly fitted to a patient's face. Breathable gas in the form of fresh air, or oxygen enriched air, enters the mask **30** by flexible tubing **32** which, in turn, is connected with a motor driven turbine **34** to which there is provided an air inlet **36**. The motor **38** for the turbine is controlled by a motor-servo unit **40** to commence, increase or decrease the pressure of air supplied to the mask **30** as CPAP treatment. The mask **30** also includes an exhaust port **42** that is close to the junction of the tubing **34** with the mask **30**.

Interposed between the mask **30** and the exhaust **42** is a linear flow-resistive element **44**. In practice, the distance between mask **30** and exhaust **42**, including flow resistive element **44** is very short so as to minimize deadspace volume. The mask side of the flow-resistive element **44** is connected by a small bore tube **46** to a mask pressure transducer **48** and to an input of a differential pressure transducer **50**. Pressure at the other side of the flow-resistive element **44** is conveyed to the other input of the differential pressure transducer **50** by another small bore tube **52**.

The mask pressure transducer **48** generates an electrical signal in proportion to the mask pressure, which is amplified by amplifier **52** and passed both to a multiplexer/ADC unit **54** and to the motor-servo unit **40**. The function of the signal provided to the motor-servo unit **40** is as a form of feedback to ensure that the actual mask static pressure is controlled to be closely approximate to the set point pressure.

The differential pressure sensed across the linear flow-resistive element **44** is output as an electrical signal from the differential pressure transducer **50**, and amplified by another amplifier **56**. The output signal from the amplifier **56** therefore represents a measure of the mask airflow. The linear flow-resistive element **44** can be constructed using a flexible-vaned iris. Alternatively, a fixed orifice can be used, in which case a linearization circuit is included in amplifier **52**, or a linearization step such as table lookup included in the operation of controller **62**.

The output signal from the amplifier **56** is low-pass filtered by the low-pass filter **58**, typically with an upper limit of 10 Hz in order to remove non-respiratory noise. The amplifier **56** output signal is also bandpassed by the bandpass filter **60**, and typically in a range of 30–100 Hz to yield a snoring signal. The outputs from both the low-pass filter **58** and the bandpass filter **60** are provided to the digitizer (ADC) unit **54**. The digitized respiratory airflow (FLOW), snore, and mask pressure (P_{mask}) signals from ADC **54** are passed to a controller **62**, typically constituted by a microprocessor based device also provided with program memory and data processing storage memory.

The controller **62** outputs a pressure request signal which is converted to a voltage by DAC **64**, and passed to the motor-servo unit **40**. This signal therefore represents the set point pressure $P_{set}(t)$ to be supplied by the turbine **34** to the mask **30** in the administration of CPAP treatment. The controller **62** is programmed to perform a number of processing functions, as presently will be described.

As an alternative to the mask pressure transducer **48**, a direct pressure/electrical solid state transducer (not shown) can be mounted from the mask with access to the space therewithin, or to the air delivery tubing **32** proximate the point of entry to the mask **30**.

Further, it may not be convenient to mount the flow transducer **44** at or near the mask **30**, nor to measure the mask pressure at or near the mask. An alternative arrangement, where the flow and pressure transducers are mounted at or near the air pressure generator (in the embodiment being the turbine **34**) is shown in FIG. **2**.

The pressure $p_g(t)$ occurring at the pressure generator **34** outlet is measured by a pressure transducer **70**. The flow $f_g(t)$ through tubing **32** is measured with flow sensor **72** provided at the output of the turbine **34**. The pressure loss along tubing **32** is calculated in element **74** from the flow through the tube $f_g(t)$, and a knowledge of the pressure-flow characteristic of the tubing, for example by table lookup. The pressure at the mask p_m is then calculated in subtraction element **76** by subtracting the tube pressure loss from $p_g(t)$.

The pressure loss along tube **32** is then added to the desired set pressure at the mask $p_{set}(t)$ in summation element **78** to yield the desired instantaneous pressure at the pressure generator **34**. Preferably, the controller of the pressure generator **34** has a negative feedback input from the pressure transducer **70**, so that the desired pressure from step **78** is achieved more accurately. The flow through the exhaust **42** is calculated from the pressure at the mask (calculated in element **76**) from the pressure-flow characteristic of the exhaust in element **80**, for example by table lookup. Finally, the mask flow is calculated by subtracting the flow through the exhaust **42** from the flow through the tubing **32**, in subtraction element **82**.

The methodology put into place by the controller **62** will now be described. In a first embodiment, there is a pressure response to apneas, but not to indicators of partial obstruction, and therefore snore detection bandpass filter **60** is not required.

An initial CPAP treatment pressure, typically 4 cmH_2O, is supplied to the subject. The FLOW signal is processed to detect the occurrence of an apnea (as will presently be discussed) and, at the same time, the P_{mask} signal is recorded. When it is determined that an apnea has occured its duration is recorded. At the same time P_{mask} is compared against a pressure threshold, P_u. If P_{mask} is at or above P_u the controller will act to maintain or reduce that pressure. If, on the other hand, P_{mask} is below P_u, the controller will act to increase the treatment pressure by an amount ΔP.

In a preferred form, ΔP is determined as follows:

$$\Delta P=[P_u-P]f(t_a) \qquad (1)$$

where

ΔP is the change in pressure (cmH_2O)

P_u is the pressure threshold, which in an embodiment can be 10 cmH_2O

P is the current treatment pressure immediately before the apnea (cmH_2O)

t_a is the apnea duration (s)

$f(t_a)$ is a function that is a monotonically increasing function of t_a, zero for $t_a=0$

FIG. **3** is a graphical representation of equation (1), showing a region below P_u where it is taken that an apnea is obstructive and demonstrating two cases of the ΔP characteristics as a function of apnea duration (ie short and longer) such that ΔP is an increasing function of apnea duration and a decreasing function of the current treatment pressure. Above P_u, it is taken that the apnea is non-obstructive, and ΔP is held to be zero for all values of the current treatment pressure.

One form of the function $f(t_a)$ is:

$$f(t_a) = \frac{rt_a}{\Delta P_{max}} \tag{2}$$

In one embodiment the parameters can be:

$r=0.13\ cmH_2O.s^{-1}$

$\Delta P_{max}=6\ cmH_2O$

Another form of the function $f(t_a)$ is:

$$f(t_a)=1-\exp(-kt_a) \tag{3}$$

In one embodiment the parameter can be $k=0.02\ s^{-1}$

FIG. **4** is a graphical representation of equation (3) for the parameters given above.

The controller **62** implements the foregoing methodology using the following pseudo-code.

```
Set apnea duration to zero
Clear "start of breath" flag
Set initial CPAP pressure to 4 cmH2O.
Set maximum delta pressure due to apnea to 6 cmH2O.
    Set top roll-off pressure to initial CPAP pressure plus maximum delta
pressure due to apnea.
    REPEAT
        Sample mask airflow (in L/sec) at 50 Hz.
        Calculate mask leak as mask airflow low pass filtered with a
  time constant of 10 seconds.
        Check for presence and duration of any apnea.
        Check for start of breath.
        IF start of breath flag set:
            IF apnea duration greater than 10 seconds AND current
        CPAP pressure less than top roll-off pressure:
                Set delta pressure for this apnea to (top roll-off
            pressure - current CPAP pressure)/maximum delta pressure
            due to apnea times 8 cmH2O per minute of apnea duration.
                Add delta pressure for this apnea to total delta
            pressure due to apnea, and truncate to maximum delta
            pressure due to apnea.
                Reset apnea duration to zero.
            ELSE
                Reduce total delta pressure due to apnea with a time
            constant of 20 minutes.
            END
            Set CPAP pressure to initial CPAP pressure plus total delta
        pressure due to apnea.
        Clear start of breath flag.
    END
END
```

This implementation is suitable for subjects in whom obstructive apneas are controlled at a CPAP pressure of less than 10 cmH_2O. Increasing the maximum delta pressure due to apnea from 6 cmH_2O to 10 cmH_2O would permit the prevention of obstructive apneas in the majority of subjects, in exchange for an increase in undesirable pressure increases due to open airway apneas.

The procedure "Check for presence and duration of any apnea" can be implemented using the following pseudocode:

```
        Calculate 2 second RMS airflow as the RMS airflow over the
  previous 2 seconds.
        Calculate longterm average RMS airflow as the 2 second RMS
  airflow, low pass filtered with a time constant of 300 seconds.
        IF 2 second RMS airflow is less than 25% of longterm average
  RMS airflow:
            Mark apnea detected and increment apnea duration by 1/50
```

-continued

```
        second.
    END
    The procedure, "Check for start of breath" is implemented by the
following pseudocode:
    IF respiratory airflow is inspiratory AND respiratory airflow on
  previous sample was not inspiratory:
        Set "start of breath" flag.
    END
```

FIG. **5** shows the above method and apparatus in operation. The mask **30** was connected to a piston driven breathing simulator set to a normal respiratory rate and depth, and programmed to introduce a 20 second apnea once per minute from the 2nd minute to the 20th minute. In operation, the pressure remained at the initial pressure of 4 cmH_2O until the first apnea, which led to a brisk increase in mask pressure. The pressure then decayed slightly during the subsequent 40 seconds of normal breathing. Subsequent apneas produced smaller increments, and the mask pressure settled out to approximately 9.5 cmH_2O. In most actual patients, the number of apneas would reduce as the pressure increased. Because the pressure due to repetitive apneas cannot exceed 10 cmH_2O, and most pressure-induced open airway apneas occur at very high pressures typically above 10 cmH_2O, this algorithm will not falsely or needlessly increase pressure in response to most pressure-induced open airway apneas, thus avoiding a vicious cycle of high pressure leading to open airway apneas leading to vet further pressure increase.

The above embodiment can be considerably improved by the addition of independent pressure increases in response to partial upper airway obstruction indicated by the presence of snoring or changes in the shape of the inspiratory flow-vs-time curve. In the majority of subjects, in whom substantial periods of snoring or flow limitation exist prior to any closed airway apneas, the CPAP pressure will increase in response to said snoring and/or changes in the shape of the inspiratory flow-vs-time curve, to a sufficient level to largely eliminate severe partial obstruction, without any apneas of any kind occurring. In those subjects in whom closed airway apneas appear with little or no prior period of partial obstruction, the first few apneas will produce a brisk increase in CPAP pressure as previously discussed, and in general this will provide sufficient partial support to the airway to permit periods of detectable partial obstruction, preventing any further apneas from occurring.

This second embodiment is implemented using the following pseudocode.

```
Set initial CPAP pressure to 4 cmH2O.
Set apnea duration to zero
  Clear "start of breath" flag
  REPEAT every 1/50 of a second
        Sample mask pressure (in cmH2O), mask airflow (in L/sec), and
snore (1 unit corresponds loosely to a typical snore).
        Calculate mask leak as mask airflow low pass filtered with a time
constant of 10 seconds.
        Adjust snore signal for machine noise.
        Check for presence and duration of any apnea.
        Check for start of breath.
        IF start of breath flag set:
            IF apnea duration greater than 10 seconds AND current
    CPAP pressure less than 10 cmH2O:
                Set delta pressure for this apnea to (10 - current
        CPAP pressure)/6 times 8 cmH2O per minute of apnea
        duration.
```

-continued

```
        Add delta pressure for this apnea to total delta
    pressure due to apnea, and truncate to 16 cmH2O
        Reset apnea duration to zero.
      ELSE
        Reduce total delta pressure due to apnea with a time
    constant of 20 minutes.
      END
      Calculate flow limitation index.
    Calculate flow limitation threshold.
    IF flow limitation index is less than said threshold:
      Set flow limitation delta pressure for this breath to 3
  cmH2O times (threshold-flow limitation index).
      Add flow limitation delta pressure for this breath to
  total delta pressure due to flow limitation, and truncate to 16
  cmH2O.
    ELSE
      Reduce total delta pressure due to flow limitation
  with a time constant of 10 minutes.
    END
    Calculate mean snore for breath.
    Calculate snore threshold.
    IF mean snore exceeds said threshold:
      set delta pressure due to snore for this breath to 3
  cmH2O times (mean snore for this breath - threshold).
      Add delta pressure due to snore for this breath to
  total delta pressure due to snore, and truncate to 16 cmH2O.
    ELSE
      Reduce total delta pressure due to snore with a time
  constant of 10 minutes.
    END
  Set CPAP pressure to 4 cmH2O plus total delta pressure
due to apnea plus total delta pressure due to snore plus total delta
pressure due to flow limitation, and truncate to 20 cmH2O.
  Clear start of breath flag.
 END
 END
```

In the above implementation, apneas can only cause the CPAP pressure to rise as far as 10 cmH_2O, but subsequently, indicators of partial obstruction can increase the CPAP pressure to 20 cmH_2O which is sufficient to treat the vast majority of subjects.

The procedure “Adjust snore for machine noise” is described by the following pseudocode:

Machine noise=*K*1*mask pressure+*K*2*mask pressure squared+*K*3*mask flow+*K*4*time derivative of mask flow+i **K5***time derivative of mask pressure.

Adjusted snore signal=raw snore signal−machine noise.

where the constants **K1** to **K5** are determined empirically for any particular physical embodiment, and for a particular machine may be zero. In other embodiments, blower fan speed measured with a tachometer or pressure at the blower may be used instead of mask pressure.

The procedure “Calculate flow limitation index” is described by the following pseudocode:

Identify the inspiratory portion of the preceding breath

Note the duration of inspiration.

Calculate the mean inspiratory airflow.

For each sample point over said inspiratory portion, calculate a normalized inspiratory airflow by dividing the inspiratory airflow by the mean inspiratory airflow.

Identify a mid-portion consisting of those sample points between 25% and 75% of the duration of inspiration.

Calculate the flow limitation index as the RMS deviation over said mid-portion of (normalized inspiratory airflow −1)

The logic of the above algorithm is as follows: partial upper airway obstruction in untreated or partially treated Obstructive Sleep Apnea syndrome, and the related Upper Airway Resistance syndrome, leads to mid-inspiratory flow limitation, as shown in FIG. **6**, which shows typical inspiratory waveforms respectively for normal and partially obstructed breaths, after scaling (normalizing) to equal mean amplitude and duration.

For a totally flow-limited breath, the flow amplitude vs. time curve would be a square wave and the RMS deviation would be zero. For a normal breath, the RMS deviation is approximately 0.2 units, and this deviation decreases as the flow limitation becomes more severe.

In some patients, it is not possible to prevent all upper airway obstruction, even at maximum pressure. In addition, there is a trade-off between the possible advantage of increasing the pressure in response to snoring and the disadvantage of increased side effects. This trade-off is implemented in procedure “calculate snore threshold” by looking up the snore threshold in the following table:

Pressure (cm H_2O)	Threshold (snore units)	Description
<10	0.2	very soft
10–12	0.25	
12–14	0.3	soft
14–16	0.4	
16–18	0.6	moderate
>18	1.8	loud

For similar reasons, the procedure “calculate flow limitation threshold” sets the flow limitation threshold to a lower value corresponding to more severe flow limitation, if the pressure is already high or if there is a large leak:

```
IF mask leak is greater than 0.7 L/sec
  set leak roll-off to 0.0
ELSE if mask leak is less than 0.3 L/sec
  set leak roll-off to 1.0
ELSE
  set leak roll-off to (0.7-mask leak)/0.4
END
Set pressure roll-off to (20-mask pressure)/16
Set flow limitation threshold to 0.15 times pressure roll-off times leak
roll-off
```

Some subjects will have occasional open airway apneas at sleep onset during stage 1 sleep and therefore at low pressure, and the above algorithm will incorrectly increase CPAP pressure in response to these events. However, such apneas are not usually repetitive, because the subject quickly becomes more deeply asleep where such events do not occur, and furthermore, the false pressure increments become smaller with repeated events. Once the subject reaches deeper sleep, any such falsely increased pressure will diminish. However, it is still advantageous to avoid falsely or needlessly increasing pressure in response to such sleep onset open airway apneas.

As previously discussed, one prior art method for avoiding unnecessary increases in pressure in response to open airway apneas is to determine the conductance of the airway during an apnea using the forced oscillation method, and only increase mask pressure if the conductance is less than a threshold. However, if the nasal airway is narrow or if the subject has lung disease, the airway conductance may be low even in the presence of an open airway and the forced oscillation method may still falsely increase pressure in response to open airway apneas. Conversely, the combination of the forced oscillation method with embodiments of the present invention has the added advantage that in most cases open airway apneas are correctly detected by the 'forced oscillation method', but in those cases where the forced oscillation method falsely reports a closed airway, the mask pressure will not increase above 10 cmH_2O, thus preventing run-away increases in pressure. This is demonstrated in a third embodiment using the following pseudocode:

```
Set apnea duration to zero
Clear "start of breath" flag
REPEAT every 1/50 of a second
    Sample mask pressure (in cmH2O), mask airflow (in L/sec), and
snore (1 unit corresponds loosely to a typical snore).
    Calculate mask leak as mask airflow low pass filtered with a time
constant of 10 seconds.
    Adjust snore signal for machine noise.
    Check for presence and duration of any apnea.
    IF apnea in progress:
      measure conductance of airway using forced oscillation
  method.
END
Check for start of breath.
IF start of breath flag set:
    IF apnea duration greater than 10 seconds AND current
CPAP pressure less than 10 cmH2O AND airway conductance
measured using forced oscillation method is less than 0.05
cmH2O/L/sec:
      Set delta pressure for this apnea to (10 - current
  CPAP pressure)/6 times 8 cmH2O per minute of apnea
  duration.
      Add delta pressure for this apnea to total delta
  pressure due to apnea, and truncate to 16 cmH2O
      Reset apnea duration to zero.
    ELSE
      Reduce total delta pressure due to apnea with a time
  constant of 20 minutes.
    END
    Calculate flow limitation index.
    Calculate flow limitation threshold.
    IF flow limitation index is less than said threshold:
      Set flow limitation delta pressure for this breath to 3
  cmH2O times (threshold-flow limitation index).
      Add flow limitation delta pressure for this breath to
  total delta pressure due to flow limitation, and truncate to 16
  cmH2O.
    ELSE
      Reduce total delta pressure due to flow limitation
  with a time constant of 10 minutes.
    END
    Calculate mean snore for breath.
    Calculate snore threshold.
    IF mean snore exceeds said threshold:
      set delta pressure due to snore for this breath to 3
  cmH2O times (mean snore for this breath - threshold).
      Add delta pressure due to snore for this breath to
  total delta pressure due to snore, and truncate to 16 cmH2O.
    ELSE
      Reduce total delta pressure due to snore with a time
  constant of 10 minutes.
    END
    Set CPAP pressure to 4 cmH2O plus total delta pressure
due to apnea plus total delta pressure due to snore plus total delta
pressure due to flow limitation, and truncate to 20 cmH2O.
    Clear start of breath flag.
END
END
```

The procedure, "measure airway conductance using the forced oscillation method" can be implemented using the following pseudocode:

Modulate airway pressure with an amplitude of 1 cmH_2O peak to peak at 4 Hz.

Measure amplitude of airflow signal at 4 Hz.

Measure component of mask pressure signal at 4 Hz.

Set conductance equal to said airflow amplitude divided by said mask pressure amplitude.

An alternate expression of the combination of an embodiment of the invention and the forced oscillation method is:

```
IF
  (a) the current pressure is low AND (b) the alternative method scores
the airway as closed, THEN score the airway as closed.
ELSE IF
  (a) the current pressure is high AND (b) the alternative method scores
the airway as open, THEN score the airway as open.
ELSE
score the apnea as of unknown type.
```

A further possible arrangement is to substitute the 'cardiogenic method' for determining airway patency for the 'forced oscillation method', also disclosed in European Publication No. 0 651 971 A1 (and U.S. Pat. No. 5,704,345).

More complex variants of CPAP therapy, such as bi-level CPAP therapy or therapy in which the mask pressure is modulated within a breath, can also be monitored and/or controlled using the methods described herein.

We claim:

1. A method for the administration of CPAP treatment pressure comprising the steps of:

supplying breathable gas to a patient's airway at an initial treatment pressure, and repeatedly:

determining a measure of respiratory airflow;

determining the occurrence of an apnea from a reduction in said measure of respiratory airflow below a threshold;

determining the duration of said apnea; and

increasing the treatment pressure by an amount which is an increasing function of the duration of said apnea, and a decreasing function of the treatment pressure immediately before said apnea.

2. CPAP treatment apparatus comprising:

a controllable flow generator operable to produce breathable gas at a pressure elevated above atmosphere;

a gas delivery tube coupled to the flow generator;

a patient mask coupled to the tube to receive said breathable gas from the generator and provide said gas, at a desired treatment pressure, to the patient's airway;

a controller operable to receive input signals and to control operation of said flow generator and hence the treatment pressure; and

sensor means located at the flow generator, in the delivery tube or at the mask that generates a signal input to said controller from which patient respiratory airflow is determined;

and wherein said controller is operable to determine the occurrence of an apnea from a reduction in said respiratory airflow, determine the duration of said apnea, and cause said flow generator to increase CPAP treatment pressure by an increment that is an increasing function of said apnea duration and a decreasing function of the treatment pressure immediately prior to said apnea.

3. The CPAP treatment apparatus of claim **2**, wherein there is a further determination of the occurrence of at least partial upper airway obstruction by the controller being further operable to detect the presence of characteristic changes in shape of an inspiratory flow versus time curve indicative of inspiratory airflow limitation.

4. A method for the administration of CPAP treatment pressure comprising the steps of:

supplying breathable gas to the patient's airway at a treatment pressure;

determining a measure of respiratory airflow; and determining the occurrence of an apnea from a reduction in the measure of respiratory airflow below a threshold, and, if having occurred,

(i) determining the duration of the apnea; and

(ii) increasing the treatment pressure by an amount which is an increasing function of the duration of the apnea, and a decreasing function of the treatment pressure immediately before the apnea.

5. The method of claim **4**, wherein the increase in treatment pressure is substantially zero if the treatment pressure before the apnea exceeds a pressure threshold.

6. The method of claim **5**, wherein the increase in pressure below the pressure threshold is an increasing function of the duration of the apnea, multiplied by the difference between the pressure threshold and the current treatment pressure.

7. The method of claim **6**, wherein said increasing function of apnea duration is linear on apnea duration.

8. The method of claim **5**, in which the pressure threshold is substantially 10 cm H2O.

9. The method of claim **4**, wherein the occurrence of an apnea is determined by the steps of: calculating the RMS respiratory airflow over a short time interval; calculating the RMS respiratory airflow over a longer time interval; and determining an apnea if the RMS respiratory airflow over the short time interval is less than a predetermined fraction of the RMS respiratory airflow over the longer time interval.

10. The method of claim **4**, comprising the further step of reducing the treatment pressure towards an initial treatment pressure in the absence of a further apnea.

11. The method of claim **4**, comprising the further steps of: in the absence of an apnea, determining the presence of partial obstruction; and if present, increasing the treatment pressure.

12. The method of claim **11**, in which the presence of partial obstruction is determined from the shape of the patient's inspiratory flow vs time curve.

13. The method of claim **11**, in which the presence of partial obstruction is determined from the presence of snoring.

14. The method of claim **11**, in which the presence of partial obstruction is determined from both the shape of the patient's inspiratory flow vs time curve, and from the presence of snoring.

15. The method of claim **14**, in which the patency of the airway is determined by the presence of a cardiogenic component in the respiratory airflow.

16. The method of claim **14**, in which the patency of the airway is determined by the steps of: modulating the treatment pressure at a known frequency; measuring the component of the respiratory airflow at said modulation frequency; calculating the conductance of the airway as the ratio of the amplitude of said component of the respiratory airflow to the amplitude of the mask pressure modulation; and determining that the airway is patent if the conductance exceeds a conductance threshold.

17. The method of claim **4**, comprising the further steps of: if an apnea is occurring, determining whether the patient's airway is patent during the apnea; and if the airway is patent, setting the increase in treatment pressure to zero.

* * * * *